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Mobility in Patients with Venous Leg Ulceration

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Objectives. *To compare mobility in patients with venous leg ulcers to matched controls and determine the influence of mobility, age and ulcer size on ulcer healing.*
Methods. *25 leg ulcer patients, and 25 matched controls wore a mobility monitor (ActivPAL™, PAL Technologies Ltd, Glasgow, Scotland)) which recorded the number of steps and amount of time spent walking, standing, sitting or lying for a one-week period. A walking index was calculated. The ulcer group were treated with compression bandaging and ulcer healing recorded over 12 weeks.*
Results. *There were 13 female subjects in each group. The median age was 70.5 (range 30–89) years. There was no difference in the amount of time either group spent standing, walking and resting. There was a significant reduction in the number of steps taken and in the walking index in the ulcer group compared to controls (ulcer group, median 6,685 steps/day, range 2074–17,999; control group median 8750, range 4917–16,043,* $p < 0.05$*, Mann Whitney u test). Smaller ulcers and ulcers of recent onset were most likely to heal within 12 weeks (*$p = 0.005$ *and* $p = 0.011$ *respectively, Chi squared test). The percentage of time spent mobilising and resting did not influence ulcer healing (*$r_s = -0.125$; $p = 0.55$*).*
Conclusions. *Mobility patterns among patients with leg ulcers are not significantly different to age matched controls. Ulcer patients take fewer steps per week compared to controls indicating they have reduced calf muscle pump function. Further studies are required to determine whether therapies which increase calf muscle activity have a role in ulcer treatment.*

Keywords: Venous ulceration; Mobility; Calf muscle pump; Accelerometer.

Introduction

Chronic venous disease is often associated with failure of the calf muscle pump mechanism affecting the deep leg veins.[1–3] Patients with venous leg ulcers have significantly poorer calf muscle pump function than those with no history of venous disease.[2,4] Because patients with venous leg ulcers frequently have impaired calf muscle pump function, leg ulcer patients are advised to perform leg and foot exercises, which will theoretically optimise calf muscle contraction, reduce venous hypertension and accelerate the rate of ulcer healing.

This study aimed to compare mobility levels in patients with venous leg ulcers to age and gender matched controls. Determining mobility among this patient group is important to determine whether therapies which increase calf muscle activity may have a role in ulcer treatment. We hypothesised that increased levels of calf muscle activity would correlate with better ulcer healing rates. Secondly, we observed the influence of other factors including ulcer size, ulcer duration and patients age on ulcer healing.

Methods

Thirty-two consecutive patients presenting for leg ulcer assessment were invited to participate in this study. Inclusion criteria specified that the ulcer was venous in origin with diagnosis by clinical examination and ABPI ≥ 0.80; the current ulcer should not have been previously treated with high compression bandaging; ulcer size was between 1 cm^2 and 40 cm^2 and located between the knee and ankle. Patients were excluded if they were diabetic or had a co-existing mobility problem, e.g. major joint arthritis, had a body

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mass index (BMI) of ≥35. Ulcer patients who completed the study were age and gender matched to subjects who had no clinical evidence or history of varicose vein surgery or leg ulceration. The inclusion/exclusion criteria for the control age-matched group were otherwise the same as the leg ulcer patients. The control group was recruited from the general population who matched the inclusion criteria. Informed consent was obtained from all participants prior to commencing the study.

Each study participant wore an accelerometer based mobility monitor (activPAL™, PAL Technologies Ltd, Glasgow, Scotland) continuously for a one-week period. This monitor is a miniature electronic device designed to quantify free living daily activities (Fig. 1). The activPAL™ uses an accelerometer to sense limb position and activity. From this information it can reliably discriminate periods of time spent in upright activities from seated or lying activities. Furthermore, the number of steps and the stepping rate of upright activities can be accurately recorded.[5,6] We also calculated a ''walking index'' (mean steps per week X mean stepping rate) as a reflection of a patient's total walking activity over a week long period. The activPAL™ was positioned on the subjects thigh approximately one third of the way between the hip and knee joints as recommended by the manufacturers. This monitor was held in place using PALstickies™, which are a dual layer hydrogel adhesive, which allow skin adhesion on one side and device adhesion on the other. Activity over the seven day period was recorded and the mean percentage time spent each day in the upright position, mobilising or resting was calculated. The number of steps taken each day and over the week period was also recorded. We also calculated a ''walking index'' (mean steps per week X mean stepping rate) as a reflection of a patient's total walking activity over a week long period.

Fig. 1. ActivPAL™ accelerometer positioned on a patient's thigh.

The ulcer patient group were all treated with multilayer high compression bandaging (either Profore™ or Proguide™ both Smith & Nephew). Treatment was commenced in the vascular leg ulcer clinics and continued in the community by the patient's public health nurse. The patients returned to the leg ulcer clinic at regular 4 weekly intervals for follow-up study assessment. Ulcer healing was followed for a period of 12 weeks, ulcer measurements were recorded using a tracing grid and digital planimetry at baseline prior to commencing treatment and after 4, 8 and 12 weeks of treatment with compression bandaging. Pain was assessed at recruitment using a verbal categorical rating as ''no pain'', ''mild pain'', ''moderate pain'' or ''severe pain''.

Statistical analyses

Statistical analyses were carried out using SPSS, Version 11. Means (standard deviations) and medians (range) were used to summarise normal data and skewed data, respectively. Non-parametric testing was used in all analyses; the Mann Whitney U test was used to analyse differences between groups and the Wilcoxon signed ranks test was used for paired samples. Chi-squared testing was used to determine association between categorical data. Scatter plots were mapped and Spearman's rank correlation coefficient applied to determine relationships between the various variables. A p value of <0.05 was considered statistically significant.

Ethical approval was obtained from the Research Ethics Committees at the Mid-Western Regional Hospital, Limerick and at the University of Limerick, Ireland.

Results

Thirty-two patients consented to participate in this study. One patient withdrew consent to participate while wearing the monitor and another patient was withdrawn due to their inability to leave the monitor in place for the defined study period. A further five patients were withdrawn due to a change in study treatment; these patients all developed infections requiring systemic antibiotics and treatment with high compression was discontinued until the infection was resolved due to increasing pain. The remaining 25 patients were used for the study analysis. These 25 patients were age and gender matched to 25 recruits who formed the control group. Mean BMI of

the patients was 28.2 (SD 3.7). Twenty-three patients were fully mobile and two walked with the assistance of a walking stick. There was no statistical difference in age between ulcer and control groups ($p = 0.961$). Of the control group twenty-four were fully mobile and one lady walked with the aid of a walking stick, this recruit was matched to one of the ulcer patients who also used a walking stick. Mean BMI for the control group was 25.5 (SD 3.6).

Mobility comparison results

The 50 participants were monitored over a seven-day period. There was a significant correlation between overall percentage of time spent in upright activities and the number of steps taken over the seven-day period ($r_s = 0.526$; $p = <0.001$) (Fig. 2).

The median percentage of time the study patients spent in upright activities was 30.8% (range 8.4–30.6) with the remaining 69.2% (range 49.4–91.6) spent resting, either sitting or lying during the study period. The median percentage of time the control group spent in upright activities was 27.7% (range 17.7–42.6) with the remaining 72.3% (range 57.4–82.3) spent resting. There was no statistical difference in the time spent actively mobilising or resting between groups (Mann-Whitney U test $p = 0.580$ and $p = 0.432$, respectively).

The median number of steps taken daily in the patient group was 6,685 (range 2074–17,999). In comparison, the median number of steps taken daily in the control group was 8750 (range 4917–16,043). The difference between groups in the number of steps taken was statistically significant with the ulcer group taking significantly fewer steps each day than their age matched controls ($p = 0.029$, Mann-Whitney). The median rate of stepping for the ulcer and control groups was 53.4 (range 40.1–83.3) and 58.1 (range 46.5–74.5) steps per minute, respectively ($p = 0.197$, Mann-Whitney). The median walking index (mean steps/week x mean stepping rate) for the ulcer group was 2,561,037 (range 702,768–7,745,997) compared to 3,387,894 (range 1,747,261–6,937,142) ($p = 0.026$).

Further analysis of the stepping rate between the healthy control group and the ulcer group focusing on occasional steps (<20 continuous steps), short walk steps (20–100 continuous steps) and continuous walk steps (>100 continuous steps) using similar analysis to Eifell *et al*. (2006).[7] The ulcer group took comparable occasional steps but fewer short walk and continuous walk steps than the control group (Fig. 3). Overall the number of steps taken daily and increasing age had a significant negative linear correlation with older patients taking fewer steps than younger patients ($r_s = -0.615$; $p = 0.001$) (Fig. 4). There was no significant difference between activity levels in male or female participants in the ulcer group ($p = 0.503$) or in the control group ($p = 0.347$). BMI was not shown to relate to level of activity in either ulcer or control group ($r_s = -0.056$, $p = 0.789$ and $r_s = -0.216$, $p = 0.301$ respectively). Analysis of walking activity and self reported level of pain in the ulcer group was not statistically significant ($r = -0.1526$, $p = 0.4666$).

Ulcer healing results

Baseline median ulcer size was 4.4 cm^2 (range 1.1–33.9). Seventeen patients had ulcers measuring between 1 cm^2 and 10 cm^2 (range 1.1–7.8) and eight patients presented with ulcers between 10 cm^2 and 40 cm^2 (range 15.3–33.9). Median ulcer duration prior to commencing compression bandaging was 4 months (range 1–36 months). There was no significant difference in median ulcer duration between patients with ulcers measured <10 cm^2 and those >10 cm^2

Correlations

			% Time in upright activity	Total number of steps taken during week period
Spearman's rho	% Time in upright activity	Correlation Coefficient	1.000	.526**
		Sig. (2-tailed)	.	.000
		N	50	50
	Total number of steps taken during week period	Correlation Coefficient	.526**	1.000
		Sig. (2-tailed)	.000	.
		N	50	50

**. Correlation is significant at the .01 level (2-tailed).

Fig. 2. Spearman's rho correlation between % time spent in upright activity and total no. of steps taken during study period.

	Total Steps	Occasional Steps	Short Walk Steps	Continuous walks steps
Healthy Controls	1607337	205202	645759	756016
Ulceration Group	1297892	211532	544107	542250

Average				
	Total Steps	Occasional Steps	Short Walk Steps	Continuous walks steps
Healthy Controls	64293	8208	25830	30241
Ulceration Group	51916	8461	21764	21690

Fig. 3. Number of steps taken in 168 hours (7 days) and during different walking intensities.

($p = 0.097$). Pain was reported as mild in 60% of patients ($n = 15$), moderate in 24% ($n = 6$), severe in 12% ($n = 3$) and one lady reported no pain from the ulcer. Chi-squared testing showed no significant difference between level of pain reported and ulcer size (>10 cm^2 and <10 cm^2) ($p = 0.189$).

Overall there was a significant reduction in ulcer size among the study group from baseline measurement to after 12 weeks treatment or longer ($p = <0.0001$, Wilcoxon). Eighteen (72%) patients were healed by the end of the study period of 12 weeks; of these fifteen had baseline ulcers measuring less than 10 cm^2. There was a significant difference between the number of patients with healed ulcers ($n = 15$, 88.2%) after 12 weeks treatment in the <10 cm^2 group compared to those not healed in the same group ($n = 2$, 11.8%) ($p = 0.015$). There was a reduction in ulcer size in each of the remaining seven patients with unhealed ulcers after 12 weeks treatment, which was statistically significant ($p = 0.018$). The median percentage reduction for the small initial ulcer size group was 95.6% and for the larger group it was 75.0%. Initial ulcer size produced significant differences in healing rates with smaller ulcers healing significantly faster ($r_s = -0.549$, $p = 0.005$) (Figs. 5 and 6).

Ulcer duration and the percentage reduction in ulcer size after 12 weeks treatment were also correlated significantly, those with longer standing ulcers displaying slower rates of healing ($r_s = -0.499$, $p = 0.011$). We did not see a correlation between age and percentage reduction in wound size over the study period ($p = 0.999$). BMI did not impact on the rate of ulcer healing ($r_s = -0.167$, $p = 0.425$). There was no difference in healing rates between male and female patients ($p = 0.650$).

There was a significant relationship between the initial ulcer size and time spent in upright activities; patients with larger ulcers spending less time moving and more time resting ($r_s = -0.485$; $p = 0.014$) during the study period (Fig. 6). Analyses of the overall percentage reduction in ulcer size after 12 weeks treatment did not show a statistically significant relationship with the percentage of time these patients mobilised or the time they spent resting ($r_s = -0.125$; $p = 0.552$), or the number of steps taken over the one week period ($r_s = -0.042$; $p = 0.843$).

Discussion

Calf muscle pump failure as a component of chronic venous insufficiency has been well documented. The

Correlations

			Age	Total number of steps taken during week period
Spearman's rho	Age	Correlation Coefficient	1.000	-.393**
		Sig. (2-tailed)	.	.005
		N	50	50
	Total number of steps taken during week period	Correlation Coefficient	-.393**	1.000
		Sig. (2-tailed)	.005	.
		N	50	50

**. Correlation is significant at the .01 level (2-tailed).

Fig. 4. Spearman's rho correlation between age and total no. of steps taken during study week period.

Correlations

			% reduction in wound size over 12 weeks	Initial Ulcer size
Spearman's rho	% reduction in wound size over 12 weeks	Correlation Coefficient	1.000	-.549**
		Sig. (2-tailed)	.	.005
		N	25	25
	Initial Ulcer size	Correlation Coefficient	-.549**	1.000
		Sig. (2-tailed)	.005	.
		N	25	25

**. Correlation is significant at the .01 level (2-tailed).

Fig. 5. Spearman's rho correlation between % reduction in wound size over 12 weeks and initial ulcer size.

current evidence-based conservative treatment of venous leg ulcers is compression bandaging which aims to reduce venous hypertension. As in the present study this treatment is effective in healing 50–70% of all leg ulcers after 12 weeks treatment.[8] The development of new treatments for ''slow-to-heal ulcer'' patients represents the greatest challenge to those involved in caring for patients with leg ulcers. Previous studies have not considered patient mobility as a function of calf muscle activity in patients with venous ulcers.

There have been no published studies, which have examined the role of everyday activities in ulcer healing. Although it may seem logical to anticipate that more time spent mobilising, during compression therapy would improve the rate of ulcer healing, we failed to show this. Perhaps the rate of stepping and the reduced number of steps taken in our patients with venous leg ulcers was not enough to impact on the rate of ulcer healing. The significant difference in the number of steps taken daily by the ulcer group (5492) compared to either the control group (8095) or the recommended 10,000 daily steps[9] indicates that there is a major deficit in mobility in our ulcer patients. What the normal level of mobility is in this age group requires further research.

Although our numbers are small, we found faster rates of healing among patients with smaller sized ulcers, a group that is more active than patients with larger ulcers. Perhaps their better rate of ulcer healing might be attributed to greater use of the calf muscle pump. This finding is consistent with various studies which identified the haemodynamic benefit of calf muscle pump specific exercises.[5,10] The lack of activity prior to receiving compression treatment may have resulted in ulcer deterioration and extension of ulcer size. Conversely, it is possible that the large ulcer size impeded activity. We were unable conclusively to show a significant relationship between number of steps taken daily and rate of ulcer healing. The reduction in ulcer size in patients participating in this study may simply be

Correlations

			% Time in upright activities (standing/ walking)	Initial Ulcer size
Spearman's rho	% Time in upright activities (standing/ walking)	Correlation Coefficient	1.000	-.485*
		Sig. (2-tailed)	.	.014
		N	25	25
	Initial Ulcer size	Correlation Coefficient	-.485*	1.000
		Sig. (2-tailed)	.014	.
		N	25	25

*. Correlation is significant at the .05 level (2-tailed).

Fig. 6. Spearman's rho correlation between % time in upright activities (standing and walking) and initial ulcer size.

linked to the introduction of evidence based treatment with compression bandaging and our sample size may have been too small to detect differences in rates of healing simply due to varying mobility patterns over a week period. Similarly, although younger patients in this study were shown to be active for longer periods during the day than older patients, this did not appear to affect the rate of ulcer healing.

From this small study, initial ulcer size and length of ulcer duration appear to be the most significant variables in determining the rate of ulcer healing and this observation is in keeping with previous studies.[11,12]

Time spent mobilising among patients with venous leg ulcers does not significantly differ from age matched controls. However number of steps and overall stepping activity differs significantly with ulcer patients taking fewer steps in the same period of time than the control group indicating that these patients may not be optimising use of the calf muscle pump function to a level, which may assist ulcer healing. Age and ulcer size appear to be determining factors in the amount of time spent actively mobilising, however, our results failed to show a correlation between activity and venous ulcer healing rates during compression therapy. Initial ulcer size and duration prior to compression treatment seem to be the most significant variables in determining rate of venous ulcer healing. Further research needs to explore the rate of ulcer healing in response to these calf muscle specific exercise regimens.

References

1 Christopoulos DG, Nicoladies A, Cook AN. Pathogenesis of venous ulceration in relation to calf muscle pump function. *Surg Gynecol Obstet* 1989;**106**(5):829–835.
2 Araki CT, Back TL, Padberg FT, Thompson PN, Jamil Z, Lee BC *et al*. The significance of calf muscle pump function in venous ulceration. *J Vasc Surg* 1994;**20**(6):872–879.
3 Yang D, Vandongen YK, Stacey MC. Changes in calf muscle function in chronic venous disease. *Cardiovasc Surg* 1999;**7**(4):451–456.
4 Dix FP, Brooke R, McCollum CN. Venous disease is associated with impaired range of ankle movement. *Eur J Vasc Endovasc Surg* 2003;**25**:556–561.
5 Mickelborough J, Kenney L, Moss S. Validation of a novel activity monitor. In: Conference Proceedings Recent Advances in Assistive Technology and Engineering (RAATE) 2002. Birmingham, UK; 2002. p. 9.
6 Godfrey A, Culhane KM, Lyons GM. Comparison of the performance of the activPAL™ professional physical activity logger to a discrete accelerometer-based activity monitor. *Med Eng Phys* 2006; in Press.
7 Eifell RK, Hamdy YAA, Heslop PS, Walker DJ, Lees TA. Association of 24-hour activity levels with the clinical severity of chronic venous disease. *J Vasc Surg* 2006;**44**(3):580–587.
8 Clarke Moloney M, Lyons GM, Burke P, O'Keeffe D, Grace PA. A review of technological approaches to venous ulceration. *Crit Rev Biomed Eng* 2005;**33**(6):511–556.
9 Man Kan Y, Delis K. Hemodynamic effects of supervised calf muscle exercise in patients with venous leg ulceration. *Arch Surg* 2001;**136**:1364–1369.
10 Yang D, Vandogen YK, Stacey MC. Effect of exercise on calf muscle pump function in patients with chronic venous disease. *Br J Surg* 1999;**86**:338–341.
11 Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? *Am J Med* 2000;**109**:15–19.
12 Kantor J, Margolis DJ. A multicentre study of percentage change in venous leg ulcer area as a prognostic index of healing at 24 weeks. *Br J Dermatol* 2000;**142**(5):960–964.

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